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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/960,643	09/20/2001	Thillainathan Yoganathan	KINE024	5240

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EXAMINER	
SHUKLA, RAM R	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 11/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/960,643	YOGANATHAN ET AL.	
	Examiner	Art Unit	
	Ram R. Shukla	1632	

-- Th MAILING DATE of this communication app ars on th cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 August 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3,4,6-10 and 16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *4* is/are allowed.

6)☒ Claim(s) *3,6-10 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's response and amendment filed 8-08-03 has been received and entered.

2. Claims 3,4,6-10 and 16 are pending and under consideration.

Priority

3. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

Applicants failed to address this issue. For a response to be full responsive to this office action, applicants are required to address this issue

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 16 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons of record set forth in the previous office action of 5-9-03.

Applicants' arguments filed 8-8-03 have been fully considered but they are not persuasive. Applicants argue that CaM kinase is a well-known family of enzymes and indicate to specification. However, specification also discloses that CaM kinase family is very diverse, phosphrylates a very diverse class of substrates which have very diverse functions (see paragraph 7 of the specification). In other words the number of variants will be very high and the specification does not teach how to differentiate different variants of the claimed and what will be the identifying characteristics of the species of the claimed genus. Additionally, it is emphasized that the claimed nucleic acid molecules will encompass in addition to variants of SEQ ID NO 2, any nucleic acid from any organism and the specification does not provide any description as what will be the identifying features for the claimed nucleic acids of representative organisms. Next applicants discuss example 14 of the written description guidelines to argue that claim 16 is similar to example 14 of the guidelines. However, applicants' arguments are erroneous because the two situations are not the same. In the example 14, claims recite that the polypeptides catalyze the reaction of A>B, contrary to this, there is no such limitation in claim 16. Therefore, the fact pattern of claim 16 of the instant application and example 14 can not be compared.

In conclusion, this limited information is not deemed sufficient to reasonably convey to one skilled in the art that applicant is in possession of cDNAs besides SEQ ID No 1 that encodes the amino acid sequences disclosed in SEQ ID NO 2, at the time the application was filed. Thus it is concluded that the written description requirement is not satisfied for the claimed genus.

6. Claim 16 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid that comprises the sequence set forth in SEQ ID NO 1 and that encodes the amino acid sequence of SEQ ID NO 2, does not reasonably provide enablement for other claimed embodiments for reasons of record set forth in the previous office action of 5-9-03. The specification does not enable any person skilled in the art to which it pertains,

or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The instant invention encompasses any isolated nucleic acid that encodes a mammalian CaMk-X1 polypeptide wherein said polypeptide has at least 98% sequence identity to the sequence of SEQ ID NO 2.

As noted in the previous office action, the specification is not enabling because the specification only teaches a polynucleotide of SEQ ID NO 1 that encodes the polypeptide of SEQ ID NO 2 and does not teach how to make the nucleic acids encompassed by the claimed invention. The specification does not provide any guidance as to which 2% amino acids would have been altered by an artisan to make the polypeptide such that the resultant polypeptide will retain the biological function of SEQ ID NO 2. As discussed above, the proteins would include mutants produced by deletion, substitution, and addition or nucleic acids of any organism. As discussed in the previous office action (of 8-8-03) on pages 5-7, it is recognized in the prior art that the function of a protein depends on the sequence of its amino acids in a certain pattern, conformation of the protein due to the amino acid sequence, and the functional properties of the different parts of the protein. Furthermore, while it is known that many amino acid substitutions are generally possible in any given protein, the positions within the protein's sequence where such amino acid substitutions can be made with a reasonable expectation of success are limited. Certain positions in the sequence are critical to the protein's structure/function relationship, e.g. such as various sites or regions where the biological activity resides or regions directly involved in binding, stability, or catalysis; and in providing the correct three-dimensional spatial orientation for biologically active or binding sites, or for sites which represent other characteristics/properties of the protein. These or other regions may also be critical determinants of antigenicity of the protein of interest. These regions can tolerate only relatively conservative substitutions or no substitutions (see the previous office action of 8-8-03, page 6). Applicant has provided little or no guidance beyond the mere presentation of sequence data to enable one of ordinary skill in the art to

determine, without undue experimentation, the positions in the protein which are tolerant amino acid substitutions and the nature and extent of changes that can be made in these positions in order to obtain protein that retain function.

Therefore, the specification does not provide sufficient guidance to make and use the claimed invention commensurate with the scope of the claims and therefore, limiting the scope of the claimed invention to an isolated nucleic acid that comprises the sequence set forth in SEQ ID NO 1 and that encodes the amino acid sequence of SEQ ID NO 2.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

8. Claims 1-3 and 5-10 rejected under 35 U.S.C. 102(e) as being anticipated by Tang et al (US 2002/0197679, pub date 12-26-02, effective filing date 1-20-00 and WO 200153312-A1, accession no. AAI60703, AAM41547).

Tang et al teaches a nucleic acid sequence (SEQ ID NO 4692) that has 68.9% over all identity and 99.9% local similarity with the sequence of SEQ ID NO

1 of the instant application. The nt 12-1800 of SEQ ID NO 1 of the instant application has exact match with nt 7-1795 of SEQ ID NO 4692 of the cited art except one nucleotide mismatch. In fact, the protein encoded by nt 65-1492 of SEQ ID NO 4692 has 100% sequence match with SEQ ID NO 2 of the instant application.

It is noted that due to an advertent error, SEQ ID NO 4 was used for SEQ ID NO 4692, however, the accession number AAI60703 was correctly used. It seems applicants compared SEQ ID NO 4 of the cited art with SEQ ID NO 1 of the instant application but overlooked the correct accession number used in the previous office action.

9. Claims 3 and 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Rhodes et al (GenEmbl Accession No. Q9Y3J7, 11-1-1999 or GenBank Accession NO. ALO49688, 4-21-1999).

The amino acid sequence disclosed in accession no. Q9Y3J7 has 100% sequence identity with the amino acid sequence of SEQ ID NO 2 of the instant application. The Q9Y37J protein is encoded by the nucleic acid of accession no. AL049688. Accordingly, the nucleic acid was isolated from a cDNA expression library. Accordingly, it is cloned in a vector that expresses the protein and thus have promoter and is a plasmid.

Applicants have provided a blast search result and argued that the protein reported by Rhodes et al is 497 amino acid protein and a number of amino acid differences. However, the arguments are not persuasive because search by USPTO indicates that the protein reported by Rhodes has 481 amino acids, which has 5 amino acids extra at the N-terminus and therefore, Rhodes et al anticipates claims 3 and 6-8.

10. Claim 4 is free of the prior art of record and is allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (703) 305-1677. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for TC 1600 is (703) 703-872-9306. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the William Phillips whose telephone number is (703) 305-3413.

RAM R. SHUKLA, PH.D.
PRIMARY EXAMINER

Ram R. Shukla, Ph.D.
Primary Examiner
Art Unit 1632